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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,191	03/24/2004	Ronald M. Wallach	49386//58967 CON 2 (US)	4586
21874	7590	10/04/2005		
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 10/04/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,191

Applicant(s)

WALLACH, RONALD M.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 30, 2005 has been entered.

The Examiner acknowledges the amendments to claims 1 and 5. Claims 1-6 are pending.

Terminal Disclaimer

2. The terminal disclaimer filed on March 30, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,387,058 and U.S. Patent No. 6,740,049 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayne ('992).

Bayne teaches a cervical cytology device (42) including a plurality of elongated flexible bristles (50) of approximately uniform length connected to a handle including an elongated portion (46) and a head portion (48) to form a mop-like sample collecting member. The bristles extend from the head portion in a direction that is substantially parallel to the longitudinal axis of the handle. The head portion and the elongated portion are substantially cylindrical and the head portion is of a greater diameter than the elongated portion. The bristles have a modulus of elasticity that forms a soft surface having a substantially symmetrical shape. The mop-like sample collecting member appears fully capable of obtaining a sample through a mopping action.

3. Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Fomby ('988). Fomby teaches a brush that is capable of obtaining a sample from a body cavity. The brush includes a plurality of elongated flexible bristles of approximately uniform length connected to a handle including an elongated portion and a head portion to form a mop-like sample collecting member. The bristles extend from the head portion in a direction that is substantially parallel to the longitudinal axis of the handle. The head portion and the elongated portion are substantially cylindrical. The bristles have a modulus of elasticity that forms a soft surface having a substantially symmetrical shape. The mop-like member appears fully capable of obtaining a sample through a mopping action.

3. Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Cataneo et al. ('789). Cataneo et al. teach brush that meets all of the structural limitations of the claims

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and appears fully capable of performing cervical or vaginal sampling. The brush (12) includes a plurality of elongated flexible bristles (14) of approximately uniform length connected to a handle including an elongated portion (12) and a head portion (16) to form a mop-like sample collecting member (see Fig. 1). The bristles extend from the head portion in a direction that is substantially parallel to the longitudinal axis of the handle. The head portion and the elongated portion are *substantially*. The bristles have a modulus of elasticity that forms a soft surface having a substantially symmetrical shape in that Cataneo et al. discloses that the bristles are intended to be used on the human lips. The mop-like member appears fully capable of obtaining a sample through a mopping action when no substance is contained in the handle.

Response to Arguments

4. Applicant's arguments, see pages 10-12, filed March 30, 2005, with respect to the rejection of claims 1-6 under 35 U.S.C. 102(e) as being anticipated by Peltier have been fully considered. While the Examiner does not concede Applicant's arguments to be fully persuasive, the Examiner concedes that Peltier does not discuss the bristles forming the mop-like member in the patent disclosure. The rejection of claims 1-6 under 35 U.S.C. 102(e) as being anticipated by Peltier has been withdrawn.

4. Applicant's arguments filed March 30, 2005 have been fully considered but they are not persuasive.

Applicant contends that Bayne does not teach or suggest a "device for obtaining a sample from a body cavity" which includes "a plurality of elongated flexible bristles of approximately

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uniform length defining opposing first and second bristle end portions" wherein the plurality of flexible bristles "form a mop-like sample collecting member," and are supported "in a direction substantially parallel to the longitudinal axis of the elongated portion" where "the mop-like sample collecting member is configured to obtain a sample through a mopping action," as claimed by Applicant. Applicant primarily focuses his argument on the use of the term "scrape" in Bayne and contends that mop-like sampling member of Bayne cannot be said to collect cells by a mopping action in view of that terminology. The Examiner respectfully disagrees with Applicant's contention.

Bayne teaches an exocervical cytology brush (42) that meets all of the structural limitations of the claims. In particular, the brush (42) includes a plurality of flexible bristles (50) engaged at one end thereof by a head portion (48) that is disposed on an elongate handle (46). The plurality of bristles (50) extend from a base member (head portion 48) to form a mop-like collecting member, as defined in the specification of the instant application at page 7, lines 1-2. The bristles (50) form a generally planar brushing surface and are preferably about 3/8" long (column 6, lines 8-11), indicating that the bristles are of approximately uniform length. The head portion (48) is configured to support the bristles (50) in a direction substantially parallel to the elongated portion of the handle (Figure 3). The exocervical brush (42) is capable of being used without the endocervical brush (44). The bristles (50) are "long enough to enable the brushing surface to *conform* to the surface of the exocervix, *even an irregularly shaped exocervix*" (column 6, lines 10-13), implying that the bristles will have sufficient length, flexibility or modulus of elasticity to flex in order to conform to the exocervix surface because if the bristles are hardened to the extent that some bristles penetrate the surface of an irregularly shaped

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exocervix, then the brushing surface (42) of Bayne cannot be said to “conform to the surface” of the exocervix.

Regarding Applicant's argument that Bayne's use of the word "scrape" suggests that Bayne cannot be said to collect samples through “mopping action,” the Examiner respectfully disagrees. The Examiner notes that although the specification of the instant application uses the term “mopping action” to describe how the mop-like sample collecting member of the present invention obtains a sample, there is no special definition set forth to define what a “mopping action” consists of. *Merriam-Webster's Collegiate Dictionary, Tenth Edition* (1996) defines “mopping” to mean “to clean or clear away by mopping” and “to wipe as if with a mop.” The Examiner submits that many types of mops are known, such as ones having a mopping head formed by an absorbent sponge and ones formed by a plurality of elongate, flexible bristles. Therefore, what comprises a mopping action is vague and can be broadly interpreted to mean “to wipe.” The specification of the instant application otherwise only recites that the mop-like sample collecting member is rotated by the handle at least two revolutions in order to collect the sample. The Examiner notes that the mop-like collecting member of Bayne is also intended to be rotated by the handle for two revolutions in a sample collecting procedure (column 6, lines 20-22). The test appears to be whether the mop-like sample collecting member of Bayne can be said “to wipe” the exocervix as the member rotates. *Merriam-Webster's Collegiate Dictionary, Tenth Edition* (1996) defines the verb “wipe” to mean “b: to clean or dry by rubbing c: to draw, pass, or move for or as if for rubbing or cleaning 2 a: to remove by or as if by rubbing.” In view of these definitions, irregardless of whether Bayne uses the term “scrape” to define his sampling,

it appears that Bayne removes cells by rubbing the cervix as the collecting member rotates.

Therefore, Bayne can be said to collect cells by a “mopping action.”

The Examiner notes that Applicant has provided several definitions of the term “scrape” to attempt to show that the sampling of Bayne cannot be equivalent to the mopping action of the present invention. The Examiner respectfully submits that *Merriam-Webster's Collegiate Dictionary, Tenth Edition* (1996) provides an additional definition of the verb “scrape” to mean “to move in sliding contact with a rough surface.” The Examiner submits that the surface of the cervix may be considered a rough surface at the cellular level. *The American Heritage® Dictionary of the English Language, Fourth Edition* (2000) defines “scrape” to mean “to rub (a surface) with considerable pressure” and “to draw forcefully over a surface.” In view of these alternative definitions of the word “scrape,” the Examiner asserts that the mop-like collecting member of Bayne can be said to collect by a mopping action.

In view of the foregoing, the rejection of claims 1-6 under 35 USC 102(b) as being anticipated by Bayne ('992) is maintained.

Applicant further contends that Fomby teach an animal medicine applicator brush that presumably would be of different construction than a mop-like sample collecting member for collecting cervical samples. This argument is not persuasive. The brush of Fomby clearly includes a plurality of elongated flexible bristles of approximately uniform length defining opposing first and second bristle end portions where the plurality of flexible bristles form a mop-like sample collecting member and are supported in a direction substantially parallel to the longitudinal axis of the elongated portion. The Examiner notes that claim 1 only requires that a sample be obtained from a body cavity and does not include any limitations directed to a cervix.

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There does not appear to be anything in the structure of the brush of Fomby that prevents it from being capable of being inserted into at least some body cavities. Moreover, there is nothing in the structure of the apparatus of Fomby that appears would prevent it from being capable of contacting a cervix. In view of the discussion of the term "mopping action" hereinabove, the brush of Fomby appears fully capable of obtaining a sample through a mopping action. Finally, the Examiner respectfully submits that Applicant has not provided sufficient evidence that the applicator brush of Fomby would not be suitable for use as a mop-like sample collecting member.

In view of the foregoing, the rejection of claims 1-6 under 35 USC 102(b) as being anticipated by Fomby is maintained.

New grounds of rejection are set forth hereinabove, citing Cataneo et al. which teach a brush with a mop-like member that is also believed to read on claims 1-3, 5 and 6 of the instant application.

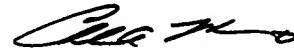
Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
September 30, 2005